



Billing Code: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-13-0850]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call (404) 639-7570 or send an email to omb@cdc.gov. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

Laboratory Response Network (LRN)-0920-0850-Extension (expiration 5/31/13)-National Center for Emerging and Zoonotic Infections (NCEZID), Centers for Disease Control and Prevention (CDC) .

Background and Brief Description

The Laboratory Response Network (LRN) was established by the Department of Health and Human Services (HHS), Centers for Disease Control and Prevention (CDC) in accordance with Presidential Decision Directive 39, which outlined national anti-terrorism policies and assigned specific missions to Federal departments and agencies. The LRN's mission is to maintain an integrated national and international network of laboratories that can respond to suspected acts of biological, chemical, or radiological threats and other public health emergencies.

When Federal, State and local public health laboratories voluntarily join the LRN, they assume specific responsibilities and are required to provide information to the LRN Program Office at CDC. Each laboratory must submit and maintain complete information regarding the testing capabilities of the laboratory. Biennially, laboratories are required to review, verify and update their testing capability information. Complete testing capability information is required in order for the LRN Program Office to determine the ability of the Network to respond to a biological or chemical threat event. The sensitivity of all information associated with the LRN requires the LRN Program Office to obtain personal information about all individuals accessing the LRN Web site. In addition, the LRN

Program Office must be able to contact all laboratory personnel during an event so each laboratory staff member that obtains access to the restricted LRN Web site must provide his or her contact information to the LRN Program Office.

As a requirement of membership, LRN Laboratories must report all biological and chemical testing results to the LRN Program at CDC using a CDC developed software tool called the LRN Results Messenger. This information is essential for surveillance of anomalies, to support response to an event that may involve multiple agencies and to manage limited resources. LRN Laboratories must also participate in and report results for Proficiency Testing Challenges or Validation Studies. LRN Laboratories participate in multiple Proficiency Testing Challenges, Exercises and/or Validation Studies every year consisting of five to 500 simulated samples provided by the LRN Program Office. It is necessary to conduct such challenges in order to verify the testing capability of the LRN Laboratories. The rarity of biological or chemical agents perceived to be of bioterrorism concern prevents some LRN Laboratories from maintaining proficiency as a result of day-to-day testing. Simulated samples are therefore distributed to ensure proficiency across the LRN. The results obtained from testing

these simulated samples must also be entered into Results Messenger for evaluation by the LRN Program Office.

During a surge event resulting from a bioterrorism or chemical terrorism attack, LRN Laboratories are also required to submit all testing results using LRN Results Messenger. The LRN Program Office requires these results in order to track the progression of a bioterrorism event and respond in the most efficient and effective way possible and for data sharing with other Federal partners involved in the response. The number of samples tested during a response to a possible event could range from 10,000 to more than 500,000 samples depending on the length and breadth of the event. Since there is potentially a large range in the number of samples for a surge event, CDC estimates the annualized burden for this event will be 2,250,000 hours or 625 responses per respondent.

There is no cost to the respondents other than their time. The total estimated annualized burden is 2,382,300 hours.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs)
Public Health Laboratories	Biennial Requalification	150	1	2
Public Health Laboratories	General Surveillance Testing Results	150	25	24
Public Health Laboratories	Proficiency Testing/Validation Testing Results	150	5	56
Public Health Laboratories	Surge Event Testing Results	150	625	24

DATE: February 26, 2013

Ron A. Otten, Ph.D.
Director, Office of Scientific Integrity
(OSI)
Office of the Associate Director for Science
(OADS)
Office of the Director
Centers for Disease Control and Prevention

[FR Doc. 2013-04900 Filed 03/01/2013 at 8:45
am; Publication Date: 03/04/2013]